TOILET GOODS ASSOCIATION, INC., ET AL. *v.* GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT.

No. 336. Argued January 16, 1967.—Decided May 22, 1967.

Pursuant to the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act, the Commissioner of Food and Drugs, by delegation from the Secretary of Health, Education, and Welfare, issued a regulation which provided that where a person has refused to permit Food and Drug employees free access to all manufacturing facilities and processes used in preparing color additives, the Commissioner "may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken." Petitioners, cosmetics distributors, manufacturers, and an association of cosmetics manufacturers, challenged this regulation and three others on the ground that the Commissioner exceeded his authority under the Act, and maintained that this regulation is impermissible since the Food and Drug Administration has long sought congressional authorization for free access to facilities, processes and formulae, which was denied except for prescription drugs. The District Court held that the Act did not prohibit this type of pre-enforcement action, that a case and controversy existed, that the issues were justiciable, and that the Government presented no reasons to warrant declining jurisdiction on discretionary grounds. In light of a later conflicting decision by the Court of Appeals for the Third Circuit in *Abbott Laboratories* v. *Celebrezze,* 352 F. 2d 286, the District Court reaffirmed its rulings but certified the question of jurisdiction to the Court of Appeals for the Second Circuit. The Court of Appeals sustained the Government's contention that judicial review was improper as to the regulation involved here, although it affirmed the District Court's judgment that it had jurisdiction as to the other challenged regulations. *Held:* Pre-enforcement judicial review of the regulation involved here is not appropriate as the controversy is not ripe for adjudication under the standards set forth in *Abbott Laboratories* v. *Gardner, ante,* p. 136. Pp. 160–166.

(a) The legal issue as presently framed is not appropriate for judicial resolution, as it is not known whether or when the Commissioner will order an inspection, what reasons he will give to justify his order, and whether the statutory scheme as a whole, notwithstanding Congress' refusal to include a specific statutory section authorizing such inspections, justified promulgation of the regulation. Pp. 162–164.

(b) The regulation will not affect the primary conduct of petitioners' business and since only minimal, if any, adverse consequences will face petitioners if they challenge the regulation upon enforcement, they should exhaust the administrative process before obtaining judicial review. Pp. 164–166.

360 F. 2d 677, affirmed.

Edward J. Ross argued the cause and filed a brief for petitioners.

Nathan Lewin argued the cause for respondents. With him on the briefs were *Solicitor General Marshall, Assistant Attorney General Vinson, Beatrice Rosenberg, Jerome M. Feit* and *William W. Goodrich.*

MR. JUSTICE HARLAN delivered the opinion of the Court.

Petitioners in this case are the Toilet Goods Association, an organization of cosmetics manufacturers accounting for some 90% of annual American sales in this field, and 39 individual cosmetics manufacturers and distributors. They brought this action in the United States District Court for the Southern District of New York seeking declaratory and injunctive relief against the Secretary of Health, Education, and Welfare and the Commissioner of Food and Drugs, on the ground that certain regulations promulgated by the Commissioner exceeded his statutory authority under the Color Additive Amendments to the Federal Food, Drug, and Cosmetic Act, 74 Stat. 397, 21 U. S. C. §§ 321–376. The District Court held that the Act did not prohibit this type of pre-enforcement suit, that a case and controversy existed, that

the issues presented were justiciable, and that no reasons had been presented by the Government to warrant declining jurisdiction on discretionary grounds. 235 F. Supp. 648. Recognizing that the subsequent decision of the Court of Appeals for the Third Circuit in *Abbott Laboratories* v. *Celebrezze,* 352 F. 2d 286, appeared to conflict with its holding, the District Court reaffirmed its earlier rulings but certified the question of jurisdiction to the Court of Appeals for the Second Circuit under 28 U. S. C. § 1292 (b). The Court of Appeals affirmed the judgment of the District Court that jurisdiction to hear the suit existed as to three of the challenged regulations, but sustained the Government's contention that judicial review was improper as to a fourth. 360 F. 2d 677.

Each side below sought review here from the portions of the Court of Appeals' decision adverse to it, the Government as petitioner in *Gardner* v. *Toilet Goods Assn.,* No. 438, and the Toilet Goods Association and other plaintiffs in the present case. We granted certiorari in both instances, 385 U. S. 813, as we did in *Abbott Laboratories* v. *Gardner,* No. 39, 383 U. S. 924, because of the apparent conflict between the Second and Third Circuits. The two *Toilet Goods* cases were set and argued together with *Abbott Laboratories.*

In our decisions reversing the judgment in *Abbott Laboratories, ante,* p. 136, and affirming the judgment in *Gardner* v. *Toilet Goods Assn., post,* p. 167, both decided today, we hold that nothing in the Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, bars a preenforcement suit under the Administrative Procedure Act, 5 U. S. C. §§ 701–704 (1964 ed., Supp. II), and the Declaratory Judgment Act, 28 U. S. C. § 2201. We nevertheless agree with the Court of Appeals that judicial review of this particular regulation in this particular context is inappropriate at this stage because, applying

the standards set forth in *Abbott Laboratories* v. *Gardner,* the controversy is not presently ripe for adjudication.

The regulation in issue here was promulgated under the Color Additive Amendments of 1960, 74 Stat. 397, 21 U. S. C. §§ 321–376, a statute that revised and somewhat broadened the authority of the Commissioner to control the ingredients added to foods, drugs, and cosmetics that impart color to them. The Commissioner of Food and Drugs, exercising power delegated by the Secretary, 22 Fed. Reg. 1051, 25 Fed. Reg. 8625, under statutory authority "to promulgate regulations for the efficient enforcement" of the Act, § 701 (a), 21 U. S. C. § 371 (a), issued the following regulation after due public notice, 26 Fed. Reg. 679, and consideration of comments submitted by interested parties:

> "(a) When it appears to the Commissioner that a person has:
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> . . . . .
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> "(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived;
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> "he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken." 28 Fed. Reg. 6445–6446; 21 CFR § 8.28.[1]

[1] The Color Additive Amendments provide for listings of color additives by the Secretary "if and to the extent that such additives are suitable and safe . . . ." § 706 (b)(1), 21 U. S. C. § 376 (b)(1). The Secretary is further authorized to provide "for the certification, with safe diluents or without diluents, of batches of color additives . . . ." § 706 (c), 21 U. S. C. § 376 (c). A color additive is "deemed unsafe" unless it is either from a certified batch or

The petitioners maintain that this regulation is an impermissible exercise of authority, that the FDA has long sought congressional authorization for free access to facilities, processes, and formulae (see, *e. g.*, the proposed "Drug and Factory Inspection Amendments of 1962," H. R. 11581, 87th Cong., 2d Sess.; Hearings before the House Committee on Interstate and Foreign Commerce on H. R. 11581 and H. R. 11582, 87th Cong., 2d Sess., 67–74; H. R. 6788, 88th Cong., 1st Sess.), but that Congress has always denied the agency this power except for prescription drugs. § 704, 21 U. S. C. § 374. Framed in this way, we agree with petitioners that a "legal" issue is raised, but nevertheless we are not persuaded that the present suit is properly maintainable.

In determining whether a challenge to an administrative regulation is ripe for review a twofold inquiry must be made: first to determine whether the issues tendered are appropriate for judicial resolution, and second to assess the hardship to the parties if judicial relief is denied at that stage.

As to the first of these factors, we agree with the Court of Appeals that the legal issue as presently framed is not appropriate for judicial resolution. This is not because the regulation is not the agency's considered and formalized determination, for we are in agreement with petitioners that under this Court's decisions in *Frozen Food Express* v. *United States,* 351 U. S. 40, and *United States* v. *Storer Broadcasting Co.,* 351 U. S. 192, there can be no question that this regulation—promulgated in a formal manner after notice and evaluation of submitted comments—is a "final agency action" under § 10 of the Administrative Procedure Act, 5 U. S. C. § 704.

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exempted from the certification requirement, § 706 (a), 21 U. S. C. § 376 (a). A cosmetic containing such an "unsafe" additive is deemed to be adulterated, § 601 (e), 21 U. S. C. § 361 (e), and is prohibited from interstate commerce. § 301 (a), 21 U. S. C. § 331 (a).

See *Abbott Laboratories* v. *Gardner, ante,* p. 136. Also, we recognize the force of petitioners' contention that the issue as they have framed it presents a purely legal question: whether the regulation is totally beyond the agency's power under the statute, the type of legal issue that courts have occasionally dealt with without requiring a specific attempt at enforcement, *Columbia Broadcasting System* v. *United States,* 316 U. S. 407; cf. *Pierce* v. *Society of Sisters,* 268 U. S. 510, or exhaustion of administrative remedies, *Allen* v. *Grand Central Aircraft Co.,* 347 U. S. 535; *Skinner & Eddy Corp.* v. *United States,* 249 U. S. 557.

These points which support the appropriateness of judicial resolution are, however, outweighed by other considerations. The regulation serves notice only that the Commissioner *may* under certain circumstances order inspection of certain facilities and data, and that further certification of additives *may* be refused to those who decline to permit a duly authorized inspection until they have complied in that regard. At this juncture we have no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order. The statutory authority asserted for the regulation is the power to promulgate regulations "for the efficient enforcement" of the Act, § 701 (a). Whether the regulation is justified thus depends not only, as petitioners appear to suggest, on whether Congress refused to include a specific section of the Act authorizing such inspections, although this factor is to be sure a highly relevant one, but also on whether the statutory scheme as a whole justified promulgation of the regulation. See *Wong Yang Sung* v. *McGrath,* 339 U. S. 33, 47. This will depend not merely on an inquiry into statutory purpose, but concurrently on an understanding of what types of enforcement problems are encountered by the FDA, the need for various sorts of supervision in order to effec-

tuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets (see 21 CFR § 130.14 (c)). We believe that judicial appraisal of these factors is likely to stand on a much surer footing in the context of a specific application of this regulation than could be the case in the framework of the generalized challenge made here.

We are also led to this result by considerations of the effect on the petitioners of the regulation, for the test of ripeness, as we have noted, depends not only on how adequately a court can deal with the legal issue presented, but also on the degree and nature of the regulation's present effect on those seeking relief. The regulation challenged here is not analogous to those that were involved in *Columbia Broadcasting System, supra,* and *Storer, supra,* and those other color additive regulations with which we deal in *Gardner* v. *Toilet Goods Assn., post,* p. 167, where the impact of the administrative action could be said to be felt immediately by those subject to it in conducting their day-to-day affairs. See also *Federal Communications Comm'n* v. *American Broadcasting Co.,* 347 U. S. 284.

This is not a situation in which primary conduct is affected—when contracts must be negotiated, ingredients tested or substituted, or special records compiled. This regulation merely states that the Commissioner may authorize inspectors to examine certain processes or formulae; no advance action is required of cosmetics manufacturers, who since the enactment of the 1938 Act have been under a statutory duty to permit reasonable inspection of a "factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein." § 704 (a). Moreover, no irremediable adverse consequences flow from requiring a later challenge to this regulation by a manufacturer who refuses to allow this type

of inspection. Unlike the other regulations challenged in this action, in which seizure of goods, heavy fines, adverse publicity for distributing "adulterated" goods, and possible criminal liability might penalize failure to comply, see *Gardner* v. *Toilet Goods Assn., post,* p. 167, a refusal to admit an inspector here would at most lead only to a suspension of certification services to the particular party, a determination that can then be promptly challenged through an administrative procedure,[2] which in turn is reviewable by a court.[3] Such review will provide an adequate forum for testing the regulation in a concrete situation.

It is true that the administrative hearing will deal with the "factual basis" of the suspension, from which petitioners infer that the Commissioner will not entertain and consider a challenge to his statutory authority to pro-

[2] See 21 CFR §§ 8.28 (b), 130.14–130.26. We recognize that a denial of certification might under certain circumstances cause inconvenience and possibly hardship, depending upon such factors as how large a supply of certified additives the particular manufacturer may have, how rapidly the administrative hearing and judicial review are conducted, and what temporary remedial or protective provisions, such as compliance with a reservation pending litigation, might be available to a manufacturer testing the regulation. In the context of the present case we need only say that such inconvenience is speculative and we have been provided with no information that would support an assumption that much weight should be attached to this possibility.

[3] The statute and regulations are not explicit as to whether review would lie, as Judge Friendly suggested, 360 F. 2d, at 687, to a court of appeals under §§ 701 (f) and 706 (d) of the Act, or to a district court as an appeal from the Commissioner's "final order," 21 CFR § 130.26, under § 10 of the Administrative Procedure Act. See 21 CFR § 130.31; compare § 505, 21 U. S. C. § 355. For purposes of this case it is only necessary to ascertain that judicial review would be available to challenge any specific order of the Commisioner denying certification services to a particular drug manufacturer, and we therefore need not decide the statutory question of which forum would be appropriate for such review.

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mulgate the regulation.[4] Whether or not this assumption is correct, given the fact that only minimal, if any, adverse consequences will face petitioners if they challenge the regulation in this manner, we think it wiser to require them to exhaust this administrative process through which the factual basis of the inspection order will certainly be aired and where more light may be thrown on the Commissioner's statutory and practical justifications for the regulation. Compare *Federal Security Adm'r* v. *Quaker Oats Co.*, 318 U. S. 218.[5] Judicial review will then be available, and a court at that juncture will be in a better position to deal with the question of statutory authority. Administrative Procedure Act § 10 (e)(B)(3), 5 U. S. C. § 706 (2)(C).

For these reasons the judgment of the Court of Appeals is

Affirmed.

MR. JUSTICE DOUGLAS dissents for the reasons stated by Judge Tyler of the District Court, 235 F. Supp. 648, 651–652.

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case.

[For concurring opinion of MR. JUSTICE FORTAS, see *post*, p. 174.]

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[4] Petitioners also cite the Commissioner's refusal, in the context of a public hearing on certain drug regulations, to entertain objections to his statutory authority to promulgate them on the ground that "This is a question of law and cannot be resolved by the taking of evidence at a public hearing." 31 Fed. Reg. 7174.

[5] See 3 Davis, Administrative Law Treatise § 20.03, at 69 (1958).